

**REMARKS****ELECTION OF CLAIMS**

Applicants acknowledge that the Examiner has treated the response to the Restriction Requirement as an election without traverse of Group I, claims 1 and 2, and SEQ ID NO:1.

**STATUS OF THE CLAIMS**

With this amendment, claims 1 and 2 are pending in the present application and under examination.

Claim 1 has been amended to recite SEQ ID NO: 1 and to recite an additional step of identifying an amino acid sequence corresponding to the searched putative open reading frames or protein-coding sequences. Support for these amendments can be found throughout the specification, *e.g.*, at page 8, second paragraph; page 11, second paragraph; and page 57, third paragraph. Claim 2 has been amended to recite that searching will be performed by searching SEQ ID NO:1 for an initiation codon and an in-frame termination codon downstream from the initiation codon. Support for these amendments can be found throughout the specification, *e.g.*, at page 8, second paragraph, which cites various common algorithms for ORF identification; page 11, second paragraph; and page 57, third paragraph. These cited algorithms identify ORFs by first scanning the entire sequence for initiation codons and then scanning sequences downstream of the initiation codon for in-frame termination codons. Thus, Applicants assert that there is adequate support in the specification for these amendments and that no new matter has been added.

Claims 22 and 23 have been canceled without prejudice or disclaimer. Claims 3-21 and 24-82 are withdrawn as being drawn to non-elected inventions.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

**PRIORITY CLAIM**

Applicants acknowledge that the Examiner has treated the application as being a national stage entry of PCT/US00/05928 with an international filing date of 3/8/00, which claims priority from provisional application 60/132,068, filed 4/30/99.

**INFORMATION DISCLOSURE STATEMENT**

Applicants thank the Examiner for reviewing and initialing the references in the Information Disclosure Statement.

**COMPLIANCE WITH SEQUENCE LISTING REQUIREMENTS**

The Examiner asserts that a replacement sequence listing is required because sequences disclosed on pages 58 and 59 of the specification are not in the present sequence listing. Applicants file herewith a replacement sequence listing including these sequences and amend the specification to include appropriate sequence identifiers. Withdrawal of this objection is therefore respectfully requested.

**OBJECTIONS TO THE SPECIFICATION**References to Figures

The specification has been objected to on the grounds that labeling of FIGS 1-9 is inconsistent with the figures themselves. Applicants have amended the specification to disclose FIGS. 1A-1E through 9A-9E and to be consistent with the figures. Withdrawal of this objection is therefore respectfully requested.

Sequence Identifiers

The specification is also objected to on the grounds that it contains sequences on page 58 and 59 that are not identified by appropriate SEQ ID NO:s. Applicants have amended the specification at pages 58 and 59 to include these sequence identifiers. Withdrawal of this objection is therefore respectfully requested.

### Hyperlinks

The specification is also objected to on the grounds that it contains hyperlinks. Applicants have amended the specification so that the address of the website is given as text rather than as a hyperlink. Withdrawal of this objection is therefore respectfully requested.

### **REJECTION OF CLAIMS UNDER 35 U.S.C § 101**

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 as allegedly being directed to nonpatentable subject matter. Specifically, the Examiner asserts that the method claimed is merely a mathematical algorithm without concrete or tangible steps (*i.e.*, no physical steps).

This rejection is respectfully traversed. The Examiner has always had the initial burden of proving a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The newly issued Oct. 27, 2005 Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (“Guidelines”) emphasize that this doctrine applies fully to the determination of whether the claimed subject matter is patentable, explicitly stating that applicants only bear the burden of proving patentable subject matter after the Examiner identifies and states on the record the basis for why the claim is an abstract idea with no practical application. *See* Guidelines at 24. The present Office Action merely alleges that the claimed invention is an unpatentable mathematical algorithm, without further explanation. Accordingly, Applicants respectfully submit that the Examiner has failed to make a *prima facie* case for unpatentable subject matter and request withdrawal of this rejection.

Furthermore, even if the Examiner had met the initial burden, the claimed method leads to a “useful, tangible, and concrete” result, which is sufficient to demonstrate that it is patentable subject matter. As noted in the recently issued Guidelines, the mere fact that a claim includes a § 101 judicial exception (such as an abstract idea or mathematical algorithm) does not mean that the claimed invention itself is nonpatentable subject matter. *See* Guidelines at 18. In particular, the Guidelines emphasize that a claimed invention that employs a mathematical algorithm to create a “useful, tangible, and concrete” result is patentable regardless of the fact that the invention includes

nonstatutory subject matter. *See* Guidelines at 20. The focus is not on whether the *steps* taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the *result* itself is “useful, tangible, and concrete.” *See* Guidelines at 20.

The claimed invention is a method of identifying an amino acid comprising searching for putative ORFs within SEQ ID NO:1, the entire genome of *N. meningitidis* B, and identifying the amino acid sequence corresponding to the putative ORFs. The result of this claimed method is therefore amino acid sequences which can serve as antigens for a meningitis vaccine, a result that is both “tangible” and “useful”. In addition, this result is “concrete.” A “concrete” result is one that is substantially repeatable. *See* Guidelines at 22. As taught in the specification, ORFs or protein-coding sequences can be identified via various algorithms. Each algorithm takes into account various characteristics of the nucleotide sequence in order to identify likely protein-coding sequences. However, all of these algorithms take into account the presence of start and stop codons, which are one of the major determinants for locating protein-coding regions. Thus, even though each algorithm factors in different characteristics and therefore will not identify exactly the same ORFs as another algorithm, it will nevertheless identify substantially the same ORFs as other algorithms. Therefore, the result of the claimed method is substantially repeatable, regardless of the particular algorithm used to carry out the searching process. Accordingly, Applicants respectfully submit that the claimed invention employs a mathematical algorithm to produce a “useful, tangible, and concrete” result and is therefore patentable subject matter.

In view of the above remarks, Applicants respectfully request that this rejection be withdrawn.

#### **REJECTION OF CLAIMS UNDER 35 U.S.C. § 112**

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

The Examiner asserts that the use of the abbreviation “NMB” and the term “NMB open reading frames” as recited in claim 1 without further explanation is vague. In view of the above amendments, Applicants assert that the rejection is moot.

The Examiner further asserts that claim 1 “fails to recite any process step that relates to the purpose set forth in the preamble.” Applicants have amended claim 1 to recite a step of “identifying an amino acid sequence.” In view of this amendment, Applicants believe that the rejection is moot and therefore respectfully request withdrawal of the rejection.

In view of the above remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

## **REJECTION OF CLAIMS UNDER 35 U.S.C. § 102**

### **Rejection under 35 U.S.C. § 102(b) by Ribot (WO 98/17805)**

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ribot (WO 98/17805). In particular, the Examiner asserts that Ribot anticipates the claimed invention because the reference discloses a method for searching *N. meningitidis* B sequences for ORFs or protein coding sequences. (Office Action, page 6). This rejection is respectfully traversed.

It is well accepted that “a claim is anticipated only if each and every element is set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). To properly reject a claimed invention, the Examiner must make a *prima facie* showing and provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975). Thus, in order to reject a claim on anticipation grounds, the Examiner must make a *prima facie*

showing that every limitation of the claim is disclosed in a single reference. Applicants respectfully submit that the Examiner has not met his burden with respect to the Ribot reference.

Claim 1 of the instant invention recites searching for putative open reading frames or protein-coding sequences within SEQ ID NO: 1 (the entire genome of *N. meningitidis* B). Ribot does not teach searching the entire genome of NMB for ORFs. Ribot instead teaches searching for putative ORFs in portions of the genome identified via transposon mutagenesis as playing a potential role in cell adhesion/invasion. *See*, for example, page 12, lined 28-29. The Examiner asserts that the genes searched for ORFs in Ribot are the same as SEQ ID NO: 1 of the instant invention (Office Action, page 6), but fails to demonstrate this via sequence alignment or any other method. Applicants therefore respectfully request that the Examiner withdraw this rejection.

**Rejection under 35 U.S.C. § 102(b) by Brodeur (WO 96/29412)**

Claims 1 and 2 were also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brodeur (WO 96/29412). This rejection is respectfully traversed.

The Examiner asserts that Brodeur anticipates the claimed invention because the reference discloses a method for searching *N. meningitidis* sequences for ORFs or protein coding sequences. (Office Action, page 6). Similar to Ribot, Brodeur does not teach searching the entire genome of NMB for ORFs. Instead, Brodeur teaches the identification via cloning of a nucleotide sequence that corresponds to a protein of interest and then scanning an insert for ORFs. *See*, for example, page 41, lines 17-23. The Examiner asserts that the genes searched for ORFs in Brodeur are the same as SEQ ID NO: 1 of the instant invention (Office Action, page 6), but fails to demonstrate this via sequence alignment or any other method. The Examiner thus fails to meet his burden and Applicants therefore respectfully request that the Examiner withdraw this rejection.

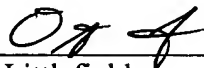
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is

determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **223002100400**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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